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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,123	11/26/2003	Theodorus Cornelis Schaap	I-1998.407 US D2	1322

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,123	SCHAAP ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *11/26/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-22 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-22 and 24-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

1. Applicant's amendment filed on 11/26/03 is acknowledged.

Claims 1-6 and 23 have been canceled.

Claims 7-22 and 24-26 have been amended.

New claims 27-29 have been added.

Claims 7-22 and 24-29 are pending in the application.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7-8 (in part), drawn to a polypeptide, classified in class, 530 subclass 350.

(Further election of invention required, see Para # 21)

II. Claims 9-15 (in part) and 27-29 (in part), drawn to a nucleic acid, classified in class 536, subclass23.1

(Further election of invention required, see Para # 21)

III. Claims 16-20 (in part) drawn to a vaccine comprising one immunogen namely polypeptide classified in class 424 subclass 184.1

(Further election of invention required, see Para # 21)

IV. Claims 16-20 (in part) drawn to a vaccine comprising live recombinant carrier comprising DNA or a host cell comprising DNA classified in class 514 subclass 44

(Further election of invention required, see Para # 21)

V. Claim 21 (in part) drawn to an antibody, classified in class 530, subclass 387.1

(Further election of invention required, see Para # 21)

VI. Claim 22 (in part) drawn to a method for preparation of antibodies comprising administering to an animal classified in class 424 subclass 130.1.

(Further election of invention required, see Para # 21)

VII Claim 24 (in part) drawn to another method for preparing a vaccine comprising mixing antibodies classified in 530, subclass 387.1

(Further election of invention required, see Para # 21)

VIII. Claim 25 (in part) drawn to a method for detection of Eimeria, classified in class 435,subclass 6.

(Further election of invention required, see Para # 21)

IX. Claim 26 (in part) drawn to a method for the detection of Eimeria antibodies, classified in class 435,subclass 7.1.

(Further election of invention required, see Para # 21)

3 Inventions I, II, III, IV and V are patentably distinct products. Group I Invention is directed to a polypeptide made of amino acids and Group II is directed to DNA, which consists of nucleic acids, which is distinct from Invention I. Invention V is drawn to an antibody, which is distinct from Inventions I-II since it has an inherent affinity, avidity, and specificity that a DNA or a simple protein is not capable of expressing. Invention III and IV are drawn to a vaccine composition comprising polypeptide or live recombinant carrier comprising DNA or a host cell comprising DNA, adjuvant and an additional poultry pathogen and is patentably distinct and different from products of inventions I, II and III since the composition not only comprises peptide or live recombinant carrier or a host cell comprising DNA but also an additional pathogen like Marek's disease virus (MDV), Avian Retrovirus, Fowl Adenovirus etc but also other agent, an adjuvant. These products are different to each other structurally, biochemically

and functionally and are drawn to patentably distinct inventions which have materially different physical and chemical properties and structures.

4. Inventions VI, VII VIII and IX are patentably distinct methods utilizing different products i.e., reagents as discussed above, different method steps that result in a different outcome.

5. Inventions VI and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products such as antibodies to T-cell receptor.

6. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used for raising antibodies or in affinity purification methods.

7. Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used for raising antibodies or in affinity purification methods.

8. Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used for raising antibodies or in affinity purification methods.

9. Inventions VI and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product such as T-cell receptor antibodies.

10. Inventions II and Inventions VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as a probe in hybridization techniques, which is a different process.

11. Inventions II and Inventions VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as a probe in hybridization techniques, which is a different process.

12. Inventions II and Inventions IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as a probe in hybridization techniques, which is a different process.

13. Inventions VI and III/IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product such as T-cell receptor antibodies.

14. Inventions III/IV and Inventions VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The process for using the product as claimed can be practiced with another materially different product such as live attenuated parasites.

15. Inventions III/IV and Inventions VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The process for using the product as claimed can be practiced with another materially different product such as live attenuated parasites.

16. Inventions III/IV and Inventions IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The process for using the product as claimed can be practiced with another materially different product such as live attenuated parasites.

17. Inventions VI and V related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product such as T-cell receptor antibodies.

18. Inventions V and Inventions VI I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The product as claimed can be used in a materially different process such as immunoassays for detecting antigens.

19. Inventions V and Inventions VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The product as claimed can be used in a materially different process such as immunoassays for detecting antigens.

20. Inventions V and Inventions IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The product as claimed can be used in a materially different process such as immunoassays for detecting antigens.

Distinct Inventions

21. This application contains claims 7-22 (in part) and 24-29(in part) directed to patentably distinct and different inventions comprising structurally proteins as represented by SEQ.ID.NOS: 1, 2, 3, 4, 5, 6 or structurally different DNA as represented by SEQ.ID.NO: 39, 40 and 41. For each group of inventions above, restriction to one of the following SEQ.ID.NO is also required under 35 USC 121. Therefore, election is required of one of inventions I – IX and one of SEQ ID NO: 1 – 6 or SEQ ID NO: 39-41.

Inventions SEQ ID NO: 1 – 6 is structurally different recombinant proteins as evidenced by its structure, i.e., the sequence identification number. Similarly, inventions SEQ ID NO: 39-41 is structurally different recombinant polynucleotides. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different polypeptides and the polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR

1.141. Thus each recombinant protein or polynucleotide SEQ ID NO: 1 – 6 or SEQ ID NO: 39-41 having its own structure would not necessarily be art on the other. .

22. Should applicant traverse on the ground that the above-mentioned SEQ.ID.NOS are not patentably distinct inventions, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

23. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821 .04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1 .1 16, amendments submitted after allowance are governed by 37 CFR 1 .312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 1 12. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be

rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C.121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

24. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not coextensive, restriction for examination purposes as indicated is proper.

25. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

27. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile

must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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